

**California State Board of Pharmacy**

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

**Board of Pharmacy
Public Meeting****June 24, 2008****Radisson Hotel
500 Leisure Lane
Sacramento, CA 95815
(916) 922-2020****Notice:**

The majority of this meeting is scheduled to discuss e-pedigree issues. However, there is a scheduling conflict. There is a concurrent hearing in the Assembly Business and Professions Committee of SB 1307 (Ridley Thomas) that carries modifications to California's e-pedigree law (the board is the sponsor of this bill). A number of attendees of the board meeting may also wish to be in the Capitol for this hearing in the early morning.

As such, to permit those individuals who wish to attend the legislative hearing to do so, and yet still attend the board's meeting --the e-pedigree portion of the meeting will begin at 11.

MEETING MATERIALS**General Announcements****1. Professionals Achieving Consumer Trust Summit**

During the week of November 17-21, 2008, the Department of Consumer Affairs will hold a summit of DCA entities and the public. Director Carrie Lopez is coordinating this forum where all boards and bureaus will hold concurrent public meetings and offer the opportunity to observe how other boards and bureaus conduct their meetings. There will also be training sessions for board members scheduled on one day.

The general schedule, which is still being developed, is:

- Tuesday, November 18, 2008: DCA Bureau and Board Meetings
- Wednesday, November 19, 2008: seminars for board members (and the public) on various items to strengthen board member and board performance

- Thursday, November 20: DCA Board and Bureau Meetings (the Board of Pharmacy's meeting is scheduled for this date)
- Friday, November 21: DCA Board and Bureau Meetings

A tentative schedule is provided in **ATTACHMENT 1**.

At this board meeting, a Sarah Boire of DCA will provide the board with an update of this summit.

The board will schedule a public discussion of SB 472 (standardized prescription container labels). The Medical Board, Dental Board and Nursing Board will have meetings concurrently on November 20, so perhaps there may be an opportunity for a joint information sharing session. Additionally, the concept of e-prescribing may also offer an opportunity for coordinated topics among the healing arts boards.

2. Presentation by Supervising Inspector Robert Ratcliff, PharmD: "Walking Through a Pharmacy Inspection"

Supervising Inspector Ratcliff will provide an overview of what a board inspector does during an inspection. This is a CE presentation that Dr. Ratcliff makes to professional associations upon request. The presentation is scheduled for 1:45 p.m. His presentation is provided in **ATTACHMENT 7**.

II. WORKGROUP ON E-PEDIGREE

A. Presentations to the Board on Electronic Pedigree Implementation

During this part of the meeting, those in attendance will be able to provide information to the board on the status of e-pedigree implementation.

In **ATTACHMENT 2** is a report prepared by the California Healthcare Foundation produced in 2007 called "Snapshot: Health Care Costs 101."

Among the findings:

- In 2007, projected national health spending was \$2.262 trillion dollars
- This is 16.2 percent of Gross Domestic Product, and is growing annually where by 2016, is projected to reach nearly 20 percent of Gross Domestic Product.
- In 2005, spending for prescription drugs was \$200 billion, which is 10 percent of health care costs, and is 5.8 percent more than was spent for prescription drugs in 2004.
- The annual amount spent per person on health care increased from \$3,783 in 1995 to \$7,498 in 2007, an increase of 77 percent.
- US health care spending far exceed that of other developed countries, both in terms of per capita spending as well as percent of GDP.
- In the last 20 years, the percent of spending on hospital care has declined (from 37.6 percent to 30.8 percent), while the share spent on prescription drugs has grown (from 5 percent to 10.1 percent).

- National health spending has been increasing at a faster pace than inflation since 1970.
- Annual growth rate increases for health care spending and specifically for prescription drugs are at their lowest increase (5.8 percent) in 20 years.
- Premium increases have slowed, but still outpace overall growth in per capita health care spending.

In **ATTACHMENT 3** are articles showing the financial size of the prescription drug market. In the US in 2006, total retail sales (e.g., not hospital) for prescription drugs filled in pharmacies was \$192,041,120,674. In California, this was \$15,837,089,019 (8.25 percent).

I also have included reports of the profits of the largest pharmaceutical companies for the last three years. For the largest three companies I have listed the profits below in billions of dollars;

	<u>2005</u>	<u>2006</u>	<u>2007</u>
Pfizer	\$11.361b	\$8.085b	\$19.337b
Johnson & Johnson	\$8.509b	\$10.411b	\$11.053b
GlaxoSmithKline	\$8.095b	\$8.753b	\$ 9.915b

The largest generic manufacturer is Teva. Teva's gross profit for 2007 was \$4.877b, and for 2006 was \$4.259b. Additional financial and economic information for this company is included in the tab section.

Also included in this tab section is a 2008 AARP report titled "*Rx Watchdog Report Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Medicare Beneficiaries 2002-2007.*" Among the findings:

- Manufacturers have raised prices of brand name prescription drugs "substantially" since Medicare Part D. Price increases for these 220 most widely used drugs exceed the rate of inflation, and were 7.1 percent (2006) and 7.4 (2007).
- On average; manufacturer prices for 169 brand name drugs on the market since 2002 increased 50.4 percent by December 2007, compared to the general inflation rate of 19 percent during the same period.

ATTACHMENT 4 contains articles on counterfeit drugs, the general focus of which is Internet sales. According to one June 10, 2008 article from Bloomberg.com "Illegal Viagra Leads 24 percent Jump in Counterfeit Medicine Seizures":

- Pfizer, the world's largest drug-maker, estimates it may be losing sales of \$2 billion a year in Viagra alone, given how much of the drug's active ingredient is produced in India and shipped abroad.

- "Over the past six years we've seen double-digit increases around the world" of counterfeit drug seizures, says a former U.S. Federal Bureau of Investigation agent who is executive director of the pharmaceutical institute.
- "Oftentimes, the drugs that are being sold emanate from China, from Russia and from India," says a New York security firm used by pharmaceutical companies to track down counterfeiters.

Also in this article are other statements regarding the production of counterfeit drugs, including:

- "Few law enforcement agencies make stopping counterfeit drugs a priority," says Novartis AG, which is investigating sales of counterfeit versions of its hypertension drug, Diovan. "When you are talking about where manufacturing is taking place, where distribution is taking place, where the printing of the counterfeit inserts and packaging is taking place, these cases are 99 percent made by the industry."

And:

- While a portion of drugs identified as counterfeit lack proper ingredients or contain incorrect and misidentified dosages, authorities have also seized chemically identical duplicates created by manufacturers in China and India and shipped to the U.S. or Europe in violation of patent laws.
- Fake versions of Pfizer's Viagra and its impotence pill competitors -- Levitra from Leverkusen, German-based Bayer AG and Schering-Plough Corp. of Kenilworth, New Jersey, and Cialis from Eli Lilly -- have been traced to manufacturers in China and India.

"Our awareness of the extent of counterfeiting came about mainly as a result of Cialis," says Lechleiter of Indianapolis-based Lilly. "But the problem is not restricted to Cialis. We've seen counterfeit versions of other Lilly products emerge in markets around the world."

Counterfeits of Lilly's top seven products, led by the anti-psychotic drug Zyprexa, and more than two million tablets of Cialis, were seized in 800 raids around the world last year, Lilly security officials say. The top seven drugs made by Lilly generated 68 percent of the company's \$17.6 billion in sales of human medicine in 2007.

- Seizures in 45 countries last year found counterfeits of Pfizer's nine best-selling drugs, including fakes of Lipitor, the cholesterol pill that accounts for one-quarter of Pfizer's \$48 billion in sales. Illegal copies of Pfizer's eight other top drugs, which account for another 30% of sales, also were seized.

Also included in this tab section is a report produced by the European Alliance for Access to Safe Medicines, which was presented at a conference in the US in early June 2008. The conference was the Global Forum on Pharmaceutical AntiCounterfeiting, and Supervising Inspector Judi Nurse and I did a presentation via video link to this meeting. The report, "The Counterfeiting Superhighway," focuses principally on Internet drug sales, where 62 percent of the medicines they

bought online from 100 web sites were fake. Ninety percent of the prescription drugs were bought without a prescription.

The last article in **ATTACHMENT 4** is a recent LA Times editorial on tracking food through the distribution systems to better enable recalls.

B. Discussion and Action Regarding SB 1307 (Ridley-Thomas)

The Board of Pharmacy is the sponsor of this bill. Several substantial amendments have been made to SB 1307 since the board's last meeting. These amendments were made as negotiations during the legislative process. A copy of the bill is provided in **ATTACHMENT 5**.

SB 1307, which will be heard June 24 in the Assembly Business and Professions Committee, now would:

1. Create a graduated implementation schedule for drug manufacturers that requires compliance with the pedigree requirement for 20 percent of drugs by January 1, 2011, 30 percent of drugs by 2013 and the remaining 50 percent of drugs by 2015 and requires manufacturers to inform the board of the drugs it designates for each implementation cycle before each the implementation date.
2. Permit the percentages required for each implementation stage to be based, at the manufacturers discretion, on either unit volume, product package type or drug product family.
3. Prohibit, beginning on January 1, 2015, any wholesaler from selling, trading, or transferring a prescription drug at wholesale without providing a pedigree, and prohibits a wholesaler from acquiring a dangerous drug without receiving a pedigree.
4. Prohibit, beginning on July 1, 2015, any pharmacy from selling, trading, or transferring a prescription drug at wholesale without providing a pedigree, and prohibits a pharmacy from acquiring a dangerous drug without receiving a pedigree.
5. Require the board to develop regulations for inference.
6. Establish grandfathering provisions for drugs already in the supply chain when the pedigree requirements kick in.
7. Exempt the following from the electronic pedigree requirement:
 - a. Radioactive drugs, as defined, for two years while the board evaluates the risk of counterfeiting or diversion of those drugs. If the board, after two years, determines there is a risk of counterfeiting or diversion of these drugs, this section and exemption will become inoperative.
 - b. Drugs that are labeled for "veterinary use only."
 - c. Medical gases (including oxygen and nitrous oxide tanks), as defined.
 - d. Solutions that are either administered intravenously for the replenishment of fluids and electrolytes (like sodium, chloride and potassium) or used to maintain the equilibrium and minerals in the body (like dextrose, amino acids

or both) or products and sterile water that are used for irrigation, reconstitution and injection.

C. Discussion and Action Regarding the Board's Heparin Recall Inspections 2008

In **ATTACHMENT 6** is a preprint of an article that will be published in the board's July newsletter on detailing the failure of the recall system to remove or quarantine recalled heparin and Digitek from pharmacies.

The board inspected all 533 licensed hospital pharmacies in California between late April and early June 2008. The Board identified 94 hospitals where recalled heparin or Digitek was found in nonquarantined areas. In 29 of these hospitals, the board identified the recalled heparin in patient care areas. The primary goal of these inspections was to ensure patients did not receive recalled products. Sanctions for failure to adhere to the recall will be pursued in the coming months.

The board also mailed letters to the board's licensed surgical clinics about heparin, and called the administrator in each location. In the case of Digitek, the board sent letters to the state's 6,000 community pharmacies to ensure these facilities initiated action to remove the product from the pharmacies and recall it from patients as the notice directed.

The board has been working with the California Department of Public Health and the FDA on these inspections and activities.

The January 2009 *The Script* the board will provide a full report of its findings. Future regulations and statutory changes may be needed to ensure future recalls have better adherence rates.

Had serialization requirements been in effect at the time of these recalls, pharmacies would have been able to identify what specific heparin or Digitek products had been delivered to the pharmacy, and by using decommissioning data for dispensed product, could have identified how many remaining products were located in the hospital.